Comparing Integrative Interventions for Chronic Pelvic Pain: A Pilot Randomized Trial

NCT07066345

IRB Approval Date: July 24, 2025

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Comparing Integrative Interventions for Chronic Pelvic Pain: A Pilot Randomized Trial

Company or agency sponsoring the study: National Institutes of Health

Principal Investigator: Sara Till, MD, MPH

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

Behavioral intervention study

We are doing a study for people with chronic pelvic pain to learn more about how we can use integrative, non-pharmacologic treatments to improve pain, function, and quality of life. We are comparing two different integrative treatments to see if one works better for specific symptoms. Both treatments are completely remote (a website or a smartphone app) and there are no in-person visits for this study. We expect the amount of time you will participate in the study will be 10 weeks.

This study involves a process called randomization. This means that the treatment you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

This study does not change your medical treatment or follow-up. Participation is completely voluntary, has no influence on your insurance benefits or usual care. You can decide not to be in this study. Alternatives to joining this study include continuing clinical care with your primary care provider, gynecologist, or chronic pelvic pain care team. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. Participation in this study may involve rare risks, including breach of confidentiality, discomfort with being asked personal questions about health history and survey completion, and symptom exacerbation. We make every effort to minimize these risks. We protect your data and confidentiality by only allowing study staff access to your data and practicing security measures for your data. You are allowed to withdraw from the study at any time. Finally,

we do not expect the program to significantly increase your symptoms. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by improving your function, pain, or quality of life. We also anticipate that the information from this study will allow us to improve treatments for chronic pelvic pain. More information will be provided later in this document.

We expect that you will be receiving study interventions and study follow-up for 10 weeks.

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this research study is to learn about how various pelvic pain symptoms may change in response to two different types of integrative, non-pharmacologic treatment strategies. We want to see either of these treatments works better for particular symptoms, such as how much pain interferes with daily activities, quality of life, sexual function, or physical function. We also want to see if patients are able to use these remote (website or smartphone app) programs easily.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You may take part in this study if you are:

- Female sex assigned at birth (cis-female or trans-gender, nonbinary)
- Between age of 18 years old and 55 years old
- Experience chronic pelvic pain that lasts for at least 14 days of each month
- Have pain that interferes with sexual function
- Are scheduled for new patient visit with the Chronic Pelvic Pain and Endometriosis Referral Clinic within the Department of OBGYN at the University of Michigan
- Must have access to the internet and have a smartphone
- Must be willing to download a commercially available app on their smartphone
- English-language proficiency

You may not participate in this study if you are/have:

- Currently pregnant
- Severe physical impairment that will prevent you from participating in an internet-based program or smartphone app (for example, complete blindness or deafness)
- Medical condition that would limit low-intensity, short-duration physical activity and gentle stretching, including cerebral palsy, severe hip or knee osteoarthritis, severe heart failure, severe COPD requiring oxygen
- Prior care within the Chronic Pelvic Pain and Endometriosis Referral Clinic within the Department of Obstetrics and Gynecology at the University of Michigan for treatment of chronic pelvic pain (seen previously but meets criteria for new patient visit because > 3 year interval since last clinic visit).

3.2 How many people are expected to take part in this study?

Up to 60 people may participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you participate in this study, you will receive access to one of two different treatment programs that may help to manage your pelvic pain symptoms. One of these treatments uses a website and the other uses a smartphone app. Both of these programs are completely remote, meaning no-in person visits or activities are required and you can use them in the privacy and comfort of your home or wherever is most convenient for you. Both use integrative treatment strategies, meaning that they do not include medications or surgery, but you can continue to use whatever other treatments you prefer during the study, including any medications or surgery recommended by your doctor. The two different programs contain slightly different information, but you get to decide which of the tools or skills you want to use and how often you want to practice the skills or visit the website or smartphone app.

This study involves a process called randomization. This means that the program you are assigned to in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing and not choosing which study group you will be in.

You will be asked to complete an online survey at several time points during this study (baseline, 4 weeks, and 8 weeks). You will also be asked to complete a very brief (2 questions) survey about pain and once per week for 8 weeks. Some patients may also be invited to participate in a virtual focus group at the 8 week time point to give more detailed feedback about their experience using the intervention. The focus group will be video and audio recorded.

During the study period, you can continue to see your medical team, including gynecologist or primary care provider and can use any treatment that is recommended by your provider. Participating in this study will not affect access to your current medical team. Participating in this study will not affect future access to your chronic pelvic pain specialist or any treatments that they recommend when you establish care.

4.2 How much of my time will be needed to take part in this study?

Both of the programs used for this study are designed to be use on a regular basis and daily use is recommended. However, you are ultimately able to decide how often, how much, or which parts of the program you choose to use.

All participants will be asked to complete an online survey at three time points during this study (baseline, 4-weeks, 8-weeks). We anticipate that it will take about 1.5 hours to complete the baseline survey and about 1 hours to complete the 4-week and 8-week surveys. All participants will be asked to complete a very brief weekly survey about pain and use of their intervention (only 2 questions), from week 1 through week 8 of the study. We anticipate that it will take about 2 minutes to complete each of these eight weekly surveys. Some patients may also be invited to participate in a virtual focus group at the 8-week time point to give more detailed feedback about their experience using the intervention. We anticipate that this virtual focus group will take about 1 hour.

4.3 When will my participation in the study be over?

Your participation in the study will last approximately ten weeks, and will be over after you complete the third survey.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- *Discomfort associated with being asked personal questions about health history and the completion of questionnaires.*
- *Symptom exacerbation (worsening):* We do not anticipate that these programs are likely to place you at an increased risk of symptom exacerbations (worsening). However, new treatments or activities sometimes cause a temporary increase in pain. This is a well-described phenomenon and is not unique to this program.

The researchers will try to minimize these risks by:

- *Question discomfort:* We will try to minimize these risks by allowing you to ask for clarification of any questions that you find to be unclear or troubling and allowing you to refuse to answer questions that you find too uncomfortable.
- *Symptom exacerbation:* We will try to minimize these risks by allowing you to decide how to use the program at your own pace. This program is not a replacement for professional medical advice, and you should contact your provider if you have urgent concerns. You can continue to access your gynecologist or primary care provider as needed and can initiate any new treatments recommended by them during this study period.

Additionally, there may be a risk involving loss of confidentiality or privacy. For example, if individuals outside this study were to discover that you were a participant in this research, or if any collected identifiable genetic or health information were disclosed to unauthorized persons, there is a risk of discrimination by employers or insurance providers. The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

Based on data from similar interventions in patients with other chronic pain conditions, we anticipate that patients who use these types of programs may see modest improvement in pain interference, sexual function, physical function, and quality of life associated with participation in this study (immediate and short-term potential benefits). It is possible that you may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. We also anticipate that the information gathered from this study will allow us learn how to best incorporate these integrative interventions to improve care for similar patients with

chronic pelvic pain. It is possible that other people with chronic pelvic pain may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Your participation in this study is completely voluntary. You will maintain the same access and follow up with your gynecologist, primary care provider, and chronic pelvic pain provider whether or not you choose to participate in this study. You can choose to begin any treatment or medication, or undergo surgery as recommended, regardless of whether you choose to participate in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

Tell us if you are thinking about stopping or decide to stop. It is important to tell us if you are thinking about stopping so any risks can be evaluated by the researchers. We will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell one of the researchers listed in Section 10 “Contact Information” (below).

You are free to end your participation partially or completely in the study. An example of partially ending your participation would be to discontinue receiving study intervention, while still allowing continuation of study follow-up procedures.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study doctor becomes aware of additional safety information this will be reported to the sponsor to comply with legal or regulatory requirements.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researchers believe that it is not in your best interest to stay in the study
- You become ineligible to participate
- Your condition changes and you need treatment that is not allowed while you are taking part in the stud.
- You do not follow instructions from the researchers

- The study is suspended or canceled

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. The procedures described in section 4.1 may include some non-research procedures. Those designated as "[Not research]" will not be paid for by the study. If you are not sure which procedures or services the study will pay for, ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

All patients will be asked to complete three longer surveys (baseline, 4-weeks, 8-weeks). You will receive $50 after you complete each of these surveys.

All patients will be asked to complete a very brief weekly survey (8 surveys from weeks 1-8). You will receive $10 after you complete each of these weekly surveys.

Some patients may also be invited to participate in a virtual focus group around the 8 week time point to give more detailed feedback about their experience using the intervention. If you participate in a focus group, you will receive $50.

You will also have continued access to your study intervention for a full year.

8.3 Who could profit or financially benefit from the study results?

The researchers do not profit or financially benefit from the study results.

The University of Michigan is receiving payments from the National Institutes of Health to support the activities that are required to conduct the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF PARTICIPANT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:
· Your name will not be used in any reports about the study
· You will be identified only by a study code
· Your identifying information will be kept secure
Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

By agreeing to use the Bend app, you are also agreeing to the terms of use. Terms of use for the bend app are located here: https://bend.com/terms

Paper copies of the screening worksheet to assess study eligibility will be stored in a locked cabinet and will not be made part of your electronic medical record. All additional study-related documents will be collected electronically, including a signed copy of this consent form and all online questionnaires, and none of these documents will be part of your electronic medical record. Signed consent forms will be stored on a University of Michigan secure drive. All questionnaire data will be entered into Qualtrics, a password protected, 21 CFR Part 11-compliant data capture system provided by the University of Michigan. All paper and electronic study documents will be retained for a minimum of three years after study completion.

This research is covered by a Certificate of Conidentiality from the National Institute of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research recrods.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with outher researchers.
- The Certificate does not stop reporting that federal, state, or loal laws require. Some examples are laws that require reporting of child or elder abuse and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring Uniter States federal or state government agency from checking records or evaluating programs.
- The Certificate does not stop disclosures requred by the federal Food and Drug Administration (FDA).
- We may also release informaiton about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://www.era.nih.gov/erahelp/CoC Ext/Content/A-introduction/Introduction.htm

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular Michigan Medicine medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and relatedinformatin for tax report purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

If your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

. Your permission does not expire unless you cancel it.You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Sara Till, MD, MPH
Mailing Address: 1500 E. Medical Center Dr. Ann Arbor, MI 48109
Telephone: 734-232-1333

Study Coordinator: Jordyn Boggan
Mailing Address: 1500 E. Medical Center Dr. Ann Arbor, MI 48109
Telephone: 734-998-0396
Email: OBGYNPelvicPain@med.umich.edu; jboggan@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)

Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of the signed and dated informed consent document.

Your signature in the next section means that you have received a copy of the following document(s):

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

12.1 What is meant by the storage, future research use, and sharing of study participants' medical information and leftover samples (sometimes referred to as biospecimens) taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information and leftover samples such as blood, tissue, saliva, and cells to use in future research. These future research uses take different basic forms, which are described below. The medical information and leftover samples may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information and leftover samples is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information and leftover samples; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information and samples would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

For purposes of this research study, your collected private information and any biospecimens will be shared with the study sponsor, National Institutes of Health, its collaborators, and associated research partners. With appropriate institutional and regulatory permissions, your collected private information and identifiable biospecimens could be used for future research with other researchers and companies, including those in other countries, with or without your consent. In addition, after identifiers are removed from your private information and any biospecimens, the information and biospecimens could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries, without your additional informed consent.

In each of the situations described below, you may later change your mind and withdraw your consent to the storage, use, and sharing of your information even if you give consent now, provided that the information can still be identified as yours, has not already been used or shared, or has not been added to your medical record. Keep in mind, however, that any information that has already been used or shared with other researchers, as well as any information that has been added to your medical record, cannot be recovered, or deleted.

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back. Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information.

We will assign your information a random code, rather than your name or any other details that others could use to identify you, before sharing it with other researchers. The study team will securely store the code key that links your coded information to you.

Researchers who wish to access your information must obtain permission to access your information.

You will not find out the results or directly benefit from future research utilizing your information. Sharing your information may contribute to research that helps others in the future.

You do not have to agree to storage and sharing of your information if you do not wish to. You may take part in this study even if you do not want us to share your information with other researchers. You will indicate your choice regarding storage and sharing of your information in a signature box at near the end of this document.

Optional collection/use of your specimens and/or information for future research

We would also like your permission to keep some of your identifiable data and medical information collected in the main study, so that it may be studied it in future research. The future research may be similar to this study or may be completely different. You can take part in the main study even if you decide not to let us keep your identifiable data and medical information for future research. If you give us your permission, we will use your identifiable data and medical information for future research. Even if you give us permission now to keep some of your identifiable data and study information collected in the study, you can change your mind later and ask us to destroy it. If you do change your mind, we will attempt to get your information and biospecimens back from the other researchers we've shared them with. However, there may be times we cannot. For example, if we are unable to tell which information and biospecimens came from you, we will not be able to get them back. Additionally, any information that has been added to your medical record cannot be deleted. Also, keep in mind that once we have analyzed your data, we may not be able to take the information out of our research study. We may share your data and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your data and medical information with other researchers, we will not be able to get it back.

There are no additional risks the future research above and beyond those already outlined in this document. Although we will do our best to protect your information and specimens, both during storage and when sharing them with others, it's possible that someone may be able to identify you from them. It's also possible that unauthorized people might gain access your information and/or specimens. To try to minimize both of these risks, we will assign your information and specimens a random code before sharing them with other researchers. The study team will securely store the code key that links your coded information and specimens to you. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements. You will not find out the results or benefit directly from future research on your data. Sharing your information and specimens may contribute to research that helps others in the future.

13. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with a member of the study team. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the researchers keep my data for future research (signature required below).

_____ No, I do not agree to let the researchers keep my data for future research (no signature).

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to participate in Focus Group via video/ audio recording/ photography solely for the purposes of this research project.

This project involves the option to participant in an online discussion group via video and/or audio recording and/or photography. Participants can express their likes or dislikes about the program during the focus group. I understand that it is my choice whether to participate in this discussion. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this focus group. If you do not consent to being recorded, you will not be able to participate in the focus group.

_____ Yes, I agree to participate in the focus group via video/audio recorded/photographed for this study.

_____ No, I do not agree to participate in the focus group via video/audio recorded/photographed for this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy):

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____